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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,125	07/23/2003	Nathaniel T. Becker	GC761-6	9520

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EXAMINER	
HANLEY, SUSAN MARIE	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
06/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/626,125	BECKER ET AL.	
	Examiner	Art Unit	
	SUSAN HANLEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-9,11-21,23-27,29-34 and 36-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-9,11-21,23-27,29-34 and 36-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/23/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/23/07 has been entered.

Claims 1, 3, 5-9, 11-21, 23-27, 29-34 and 36-42 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

The information disclosure statement filed 7/23/07 fails to comply with 37 CFR 1.97(c) because it lacks the fee set forth in 37 CFR 1.17(p). It has been placed in the application file, but the information referred to therein has not been considered.

Response to Arguments

Applicant's arguments, see pages 9-15 of the response, filed 7/23/07, with respect to the rejection(s) of claim(s) under 35 USC 112, 35 USC 102 and 35 USC 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, new ground(s) of rejection are made. The IDS was filed after the first action on the merits which was mailed on 9/21/06.

Claim Rejections - 35 USC § 112

Claims 1, 3, 5-9, 11-21, 23-27, 29-34 and 36-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "about" in claims 1, 3, 12, 14, 15, 17, 21, 23, 30, 34 and 36 is a relative term which renders the claim indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term “about” is employed to define the amount of PEO in a composition as well as the molecular weight of said PEO. The specification provide some standard for measuring that degree. That is, it is unclear if “about” means 1%, 10%, 50%, etc. Furthermore, one of ordinary skill in the art, in view of the prior art and the status of the art, would not be reasonably apprised of the degree of “about” because the prior art does not define that about” means a certain degree of deviation for the molecular weight of PEO or the amount of PEO in the claimed composition (MPEP 2173.05(b). The MPEP notes that:

> In determining the range encompassed by the term "about", one must consider the context of the term as it is used in the specification and claims of the application. Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd., 476 F.3d 1321, 1326, 81 USPQ2d 1427, 1432 (Fed. Cir. 2007). In< W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), the court held that a limitation defining the stretch rate of a plastic as “exceeding about 10% per second” is definite because infringement could clearly be assessed through the use of a stopwatch. However, the court held that claims reciting “at least about” were invalid for indefiniteness where there

> was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "about." Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).

Claims 1, 3, 12, 14, 15, 17, 21, 23, 30, 34 and 36 are rejected because the units for the concentration of PEO in a composition (e.g. "1.5%) are undefined. Hence, the claims are rendered indefinite becsue it is unclear if the if the concentration is based on "by weight", "by volume", (w/v), etc. or some other unit.

Claims 5-9, 11, 13, 16, 18-20, 24-27, 29, 31, 33, 37-42 are dependent claims that do not overcome the deficiencies of the independent claim that they are dependent therefrom.

Claim Rejections - 35 USC § 103

Claims 1, 3, 5-9, 11--21, 23-27, 29-34 and 36-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gebreselssie et al. (US 6.379,654) in view of Kiozpeoplou (US 4,407,788) and Tseng et al. (US 5,340,581).

Claims 5, 18, 25 and 36 recite preambles related to personal care items. The preambles to these claims have not been given patentable weight becsue a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Gebreselssie discloses a composition, a method of making and a method of use thereof, for an abrasive dentifrice for enhanced stain removal from a tooth comprising papain, glucoamylase, Polyox (PEO; at 0.35% by weight), sorbitol and the remaining components listed in Table V to effect teeth cleaning for this composition. The disclosure meets the limitations of a personal care product because a dentifrice is utilized by a person to improve appearance. The dentifrice removes stains from teeth, Hence it is a cleaner. The disclosure of papain, a protease, and glucoamylase meet the limitation of an enzyme as in claims 1, 11, 12, 16, 17, 20. The disclosure of PEO at 0.35% is a specie of concentration that meets the range limitations recited in claims 1, 14, 15, 21, 30, 34 and 36. The disclosure of sorbitol satisfies the limitation of an enzyme protecting agent as defined by the specification on page 13. Gebreselssie teaches that the dentifrice comprises a humectant that is preferably glycerin, sorbitol, xylitol and/or propylene glycol (col. 3, lines 35-42). The compostion is formed at room temperature. This disclosure meets the combining at about 35 degrees C, as recited in claim 32 because the specification does not define “about”. Therefore, room temperature is considered to be about 35 degrees C, in the absence of guidance by the instant specification.

Gebreselssie teaches that Polyox is a polyglycol (e.g., a polyethylene oxide) varying molecular weights. The polymer is a thickener that is compatible with proteolytic enzymes (col. 3, lines 60-67).

Gebreselssie does not teach that the Polyox is a high molecular weight polymer having a molecular weight in the range of about 0.8 x 10^6 to 4 x 10^6 or that the humectant is propylene glycol.

Kiozpeoplou discloses a dentifrice for stain removal from teeth containing a siliceous polishing material, a binding or gelling agent and polyoxyethylene glycol (PEO). The PEO comprises about 0.05%-5% by weight of the dentifrice or more preferably 0.1 -1.5% PEO (col. 3, lines 25-26). In example 1, PEO is present under the name Polyox WSR 301 which has a molecular weight of 4,000,000. Other molecular weights can be used at different concentrations to attain similar foam and feel of the product (col. 7, lines 48-59. Therefore, Kiozpeoplou discloses tht dentifrices containing an abrasive for removing teeth stains comprise high molecular weight PEO.

Tseng discloses a sustained release matrix for dental applications that comprises a an anti-microbial agent, a water soluble polymer and a water insoluble support resin (abstract). The preferred water soluble polymer is PEO, preferably Polyox having a molecular weight between 100,000 and 5,000,000. A preferred Polyox is WSR N-750 which has a molecular weight of 300,000. A PEO having a molecular weight of 300,000 meets the claimed range of “about 800,000 to 4,000,000” becsue “about” is not defined by the specification Hence, “about” is interpreted to mean within 500,000 Da. Polyox has a very low degree of toxicity and can be processed at a low temperature (col. 5, lines 1-15).

Tseng teaches that the anti-microbial agent can be a chemical such as chlorhexidine. Tseng clearly states that chlorhexidine can be replaced (i.e., a functional

equivalent) by other antibiotics as well as anti-plaque enzymes such as pancreatin, mucinases, protease-amylase, glucose oxidase, etc. (col. 11, line 60 to col. 12, line 2). In summary, Tseng discloses the combination of a high molecular weight Polyox and an anti-plaque enzyme, including a protease, for a dentifrice.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a high molecular weight Polyox having a molecular weight of 4,000,000 in the enzyme-containing abrasive dentifrice of Gebreselssie. The ordinary artisan would have been motivated to do so becsue Kiozpeoplou discloses that Polyox having a molecular weight of 4,000,000 is a desirable polymer for abrasive dentifrices for removing teeth stains. Hence, both Gebreselssie and Kiozpeoplou are directed to the same type of personal care product. Therefore, the ordinary artisan would use the recommendation of Kiozpeoplou to employ Polyox having a molecular weight of 4,000,000 in the dentifrice of Gebreselssie.

The ordinary artisan would have had a reasonable expectation that the enzyme in the dentifrice compostion of Gebreselssie would be compatible with Polyox having a molecular weight of 4,000,000 because Tseng recommends a dentifrice composition comprising high molecular weight PEO and a number of enzymes.

I would have been obvious to one of ordinary skill in the art at the time the invention was made to select propylene glycol as the humectant in the compostion of Gebreselssie. The ordinary artisan would have been motivated to do so because Gebreselssie teaches a small genus of humectants that have at least a comparable effect in a compostion. Thus, the ordinary artisan would expect that propylene glycol

would be an effective humectant. It is noted that Gebreselssie does not teach that propylene glycol is an enzyme protecting agent. An enzyme protective property is a natural property of propylene glycol. The structure of propylene glycol governs its enzyme-protecting properties. It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

It would have been obvious to the ordinary artisan a modified composition of Gebreselssie comprising an abrasive dentifrice for enhanced stain removal from a tooth containing papain, glucoamylase, Polyox having a molecular weight of 4,000,000 (at 0.35% by weight), sorbitol and the remaining components listed in Table V, would have the anti-misting reduction of the Polyox (MW of 4,000,000)-formulated compostion compared to the non-Polyox (MW of 4,000,000)-formulated composition and the Dv50 values recited in claims 7-9, this property would naturally result from the combination that results in said modified composition of Gebreselssie. See In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) *supra.*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Examiner, Art Unit 1651

/Sandra Saucier/
Primary Examiner, Art Unit 1651